Dkt. 41426-1E/JPW/SHS

#18 6/23/99 T. Gray

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Ron S. Israeli, et al.

Serial No.:

08/481,916

Group Art Unit: 1645

Filed

June 7, 1995

Examiner: S. Gucker

For

PROSTATE-SPECIFIC MEMBRANE ANTIGEN

1185 Avenue of the Americas New York, New York 10036

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

#### **DECLARATION UNDER 37 C.F.R. §1.132**

### I, Paul Kaladas, Ph.D., hereby declare that:

- I am a co-author of the abstract attached hereto as Exhibit 1, Feng et al. entitled
  "Purification and Biochemical Characterization of 7E11-C5 Prostate Carcinoma
  Associated Antigen," Proceedings of the American Association For Cancer Research,
  volume 32, March 1991.
- 2. At the time of preparation of such abstract, I was the group leader, immunochemistry, at Cytogen Corporation, responsible for development of analytical methods used in support of product development. As such, I was directly involved in the research leading to the abstract and in preparation of the abstract itself.
- 3. In order to obtain in purified form the 7E11-C5 prostate carcinoma associated antigen referred to in the Feng et al abstract, one skilled in the art would need to have an antibody such as the 7E11-C5 antibody referred to in the abstract or a

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hybridoma cell line such as the one which produces the 7E11-C5 antibody. Prior to the publication of this abstract, the 7E11-C5 prostate carcinoma associated antigen had not been isolated or characterized. In order to purify the antigen using the method described in the Feng et al abstract, one skilled in the art would need to have an antibody, such as the 7E11-C5 antibody, that binds specifically to the antigen. The abstract does not describe any properties of the antigen or procedures that would enable one skilled in the art to obtain the antigen in purified form without the use of a specific antibody such as the 7E11-C5 antibody.

I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/11/99

Paul Kaladas, Ph.D.

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1185 Avenue of the Americas New York, New York 10036

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

#### **DECLARATION UNDER 37 C.F.R. §1.132**

I, John D. Rodwell, Ph.D., hereby declare that:

- 1. I am Senior Vice President and Chief Scientific Officer of Cytogen Corporation.
- On April 20, 1989, Cytogen signed an exclusive license agreement with Julius S.
  Horoszewicz with respect to the 7E11-C5 hybridoma cell line and the 7E11-C5
  monoclonal antibody produced by this cell line.
- 3. Subsequent to signing that agreement, Cytogen received the 7E11-C5 hybridoma cell line. Prior to the issuance of U.S. Patent No. 5,162,504 on November 10, 1992, Cytogen did not distribute the 7E11-C5 hybridoma cell line to any person or entity. Also, prior to November 10, 1992 Cytogen did not distribute the 7E11-C5 monoclonal antibody made by this cell line to any person or entity other than the

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Eastern Virginia Medical School, which received it pursuant to a sponsored research agreement for the benefit of Cytogen and containing provisions, inter alia, that it would hold this material as confidential. At all times pertinent to this declaration, Cytogen maintained (and currently maintains) a formal policy that proprietary materials, such as those described herein, would be provided only pursuant to written agreements restricting the further transfer of the material and for purposes which furthered Cytogen's proprietary interests.

I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Data

John D. Rodwell, Ph.D.

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For PROSTATE-SPECIFIC MEMBRANE ANTIGEN

1125 Aware of the Americas New York, New York, 10036

Assistant Commissioner for Patouta Washington, D.C. 20231

SIR:

# DECLARATION UNDER 37 C.E.E. \$1.132

## I, Jolius S. Honoszewicz, bereby declare that:

- I see the inventor of the 7E11-C5 hybridays cell line disabout and claimed in U.S.
   Patent No. 5,162,504, issued November 10, 1992, and resigned to Cytagon Componentes.
- Prior to the November 10, 1992 issue date of my patent, I did not make publicly available the 7E11-C5 hybridams cell lime or 7E11-C5 monosloud artibody produced by this hybridams. To the best of my knowledge and belief, prior to November 10, 1992, the only persons who lead the 7E11-C5 hybridams cell lime or the 7E11-C5 memorland, antibody were (a) employees or agents of Cytogen which had title to the patent application which immed as the '504 patent or (b) the persons who received exces under an agreement with Cytogen restricting its use.

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I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and feather that these statements were made with the knowledge that willful false enterments and the like so made are particulable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false enterments may journalize the validity of the application or any patent issued thereon.

Date: 6/14/99

Jul J. Doubra HD. DHSe.